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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/157,195 12/08/93 HENCO

K P965024080

FRAN, P EXAMINER

18N1/0420

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ART UNIT PAPER NUMBER

1807

DATE MAILED: 04/20/95

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 4/30/95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 8 days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- ☒ Notice of References Cited by Examiner, PTO-892.
- ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
- ☒ Notice of Art Cited by Applicant, PTO-1449. 1 page
- ☐ Notice of Informal Patent Application, PTO-152.
- ☒ Information on How to Effect Drawing Changes, PTO-1474.
- ☐

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-26, 39-66 are pending in the application.

Of the above, claims 55-66 are withdrawn from consideration.

2. ☒ Claims 27-38 have been cancelled.

3. ☐ Claims are allowed.

4. ☒ Claims 1-26, 39-54 are rejected.

5. ☐ Claims are objected to.

6. ☐ Claims are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on                     . Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on                     , has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed                     , has been ☐ approved; ☐ disapproved (see explanation).

12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received ☐ been filed in parent application, serial no.                     ; filed on                     .

13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

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**Part III DETAILED ACTION**

The examiner acknowledges the receipt of Applicant's Amendment, Paper No. 9, filed March 1, 1995. The status of the claims is as follows: Claims 27-38 have been cancelled; new claims 39-66 are added. Claims 1-26 and 39-66 are now pending before the examiner. ✓

1. Applicant's election with traverse of Group I (Claims 1-26 and newly added claims 39-54) in Paper No. 9, filed March 1, 1995, is acknowledged. The traversal to the restriction requirement made in Paper No. 5, mailed November 30, 1994, is not found persuasive because Applicant has provided no reason therefor.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-26 and 39-54 are now examined on the merit.

I. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because it was not executed in accordance with either 37 C.F.R. § 1.66 or § 1.68.

2. This application is informal in the arrangement of the specification.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

3. Applicant is suggested to file an amendment to include the following titles in the specification at the appropriate sections:

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- (a) Title of the Invention.
- (b) Cross-References to Related Applications (if any).
- (c) Statement as to rights to inventions made under Federally-sponsored research and development (if any).
- (d) Background of the Invention.
  - 1. Field of the Invention
  - 2. Description of the Prior Art.
- (e) Summary of the Invention.
- (f) Brief Description of the Drawing.
- (g) Description of the Preferred Embodiment(s).
- (h) Claim(s).
- (i) Abstract of the Disclosure.

4. The Abstract of the Disclosure is objected to because it exceeds the limitation of 250 words and is more than one page long. Correction is required. See M.P.E.P. § 608.01(b).

✓ 5. The disclosure is objected to because of the following informalities:

Claim 1, line 15: "he" should be amended to "the."

6. Claims 1-26 and 39-54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

✓ (a) Claims 1-26 and 39-54 are vague and indefinite because they fail to recite the steps to carry out the invention's method, absent which the artisan would not know the metes and bounds of the invention. Applicant is suggested to recite the claims in a Jepson-type language wherein the improvement of the recited amplification method is specifically indicated.

(b) Claims 1-26 and 39-54 are vague and indefinite because the language, "interacts" (line 6 of Claim 1), is unclear.

(c) Claims 1-26 and 39-54 are vague and indefinite because  
✓ (1) there is no antecedent for "said substance," and (2) it is unclear as to whether the recited "measuring compartment" is the only "sealed reaction chamber means."

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(d) Claim 3 is confusing because of an improper recitation. Applicant is suggested to amend the claim using a Markush-type language.

(e) Claims 4-14, 17, 19-23 and 26 are vague and indefinite because of the recitations, "at least."

(f) Claims 4-14 and 20-23, 25 and 26 are vague and indefinite because of the language "characterized in that."

(g) Claim 4 is vague and indefinite because of the language "may be."

(h) Claims 6 and 7 are vague and indefinite because it is unclear as to whether the standard nucleic acid, to be co-amplified, is a part of or independent of the target nucleic acid to be amplified.

(i) Claim 8 is vague and indefinite because the standard nucleic acid as recited is unclear as to what is meant by the language, "natural component" and "in part."

(j) Claim 22 is vague and indefinite because it is unclear as to what type of "commercially equipment" the claim is drawn to; nor is it clear as to what is meant by "the form of microtitration equipment."

(k) Claim 23 is vague and indefinite because of the language "preferably."

(l) Claims 25 and 39-42 are vague and indefinite because of the multiple usage of the language "and/or," which makes the claimed invention unclear.

(m) Claim 26 is vague and indefinite because it is unclear as to what is meant by "on line using a data processing system."

(n) Claims 1, 4-9, 13, 14, and 20-26 are vague and indefinite because it is unclear as to the chemical structure responsible for the "spectroscopically measurable parameter."

7. Claim 5 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

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There is no antecedent basis for "the dyes" drawn in Claim 5.

8. Claim 49 is rejected under 35 U.S.C. § 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Claim 49 is identical to Claim 48.

9. Claims 1-26 and 39-54 are allowable over the prior art of record. The closest prior art is:

Jinno et al., which teaches the use of psoralen to crosslink nucleic acids;

Kingsbury et al., which teaches methods to detect DNA using chemiluminescent and fluorescent probes;

Hearst et al. (U.S. Patent No. 5,184,020), which discloses the use of psoralen and its derivatives to inactivate the template activity of nucleic acid after the polymerase chain reaction, which is to control carryover problem associated with amplification of nucleic acid.

The instant invention is neither taught nor suggested by the prior art of record. The invention is to a method to detect and quantitate nucleic acid by amplification thereof using a probe attached with a spectroscopically measurable compound, such as psoralen or its derivative, which allows the detection of signals generated from the amplification products; the entire reaction is carried out in a sealed reaction chamber means without intermittent opening.

Any inquiry concerning this communication or those earlier from the examiner should be directed to Paul B. Tran, Ph.D., whose telephone number is (703) 308-4040.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose phone number is (703) 308-0196.

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Paper related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7939.

*PS*  
Paul B. Tran, Ph.D.  
Art Unit 1807  
4/17/95

*M. Parr 4/19/95*  
MARGARET PARR  
SUPERVISOR PATENT EXAMINER  
GROUP 1800